Complete Summary

GUIDELINE TITLE

Evidence-based care guideline for inotropic support with phosphodiesterase inhibitors after arterial switch operation.

BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence-based care guideline for inotropic support with phosphodiesterase inhibitors after arterial switch operation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2006 Jan 10. 8 p. [16 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for inotropic support with phosphodiesterase inhibitors after arterial switch operation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2001 Jan 22. 9 p.

Once the guideline has been in place for four years, the development team reconvenes to explore the continued validity of the guideline. This phase can be initiated at any point that evidence indicates a critical change is needed.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Low cardiac output after arterial switch operation

GUIDELINE CATEGORY

Evaluation
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Pediatrics
Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide a clinical guideline for the use of inotropic support with phosphodiesterase inhibitors after arterial switch operation

TARGET POPULATION

These guidelines are intended primarily for use in neonates (age ≤30 days) who have undergone an arterial switch operation (with or without ventricular septal defect closure).

The guidelines do not address all considerations needed to manage those with the following:

- Significant hypotension
- Significant post-operative left ventricular outflow tract obstruction

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Physical exam
2. Monitoring of urine output and checking for presence of metabolic acidosis or lactic acidemia
3. Continuous monitoring of arterial blood pressure via arterial line
4. Continuous monitoring of left atrial pressure with a transthoracic catheter

Treatment

1. Milrinone
2. Blood pressure support with other inotropic vasopressor agents as indicated

MAJOR OUTCOMES CONSIDERED

Acute left ventricular dysfunction in the immediate post-operative period

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

To select evidence for critical appraisal by the group for the update of this guideline, the Medline, EmBase, and the Cochrane databases were searched. Evidence from 2000 and before was verified for inclusion in the guidelines. Evidence from 2001 to the present was reviewed for relevance to the clinical topics/questions to generate an unrefined, "combined evidence" database using a search strategy focused on answering clinical questions relevant to inotropic support with phosphodiesterase inhibitors following arterial switch operations and employing a combination of Boolean searching on human-indexed thesaurus terms (Medical Subject Heading [MeSH] headings using an OVID Medline interface) and "natural language" searching on human-indexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on words in the title, abstract, and indexing terms. The citations were reduced by eliminating duplicates, review articles, non-English articles, and adult articles.

The abstracts were reviewed by a methodologist to eliminate low quality and irrelevant citations. During the course of the guideline development, additional clinical questions were generated and subjected to the search process, and some relevant review articles were identified. April, 2000 was the last date for which literature was reviewed for the previous version of this guideline. The details of that review strategy are not documented. However, all previous citations were reviewed for appropriateness to this revision.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic and critical literature reviews, using a grading scale, and examined current local clinical practices.

Recommendations have been formaulated by a consensus process directed by best evidence, patient and family preference, and clinical expertise. During formulation of these guidelines, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines have been reviewed and approved by clinical experts not involved in the development process, senior management, Risk Management & Corporate Compliance, other appropriate hospital committees, and other individuals as appropriate to their intended purposes. The guideline is based, in part, on three independent reviews performed by members of Evidence-Based Care Group of Health Policy & Clinical Effectiveness at Cincinnati Children's Hospital and Medical Center (CCHMC) using AGREE criteria (Appraisal of Guidelines for Research and Evaluation).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is followed by evidence grades (A-X) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

Clinical Assessments

1. It is recommended that cardiac index be supported to maintain normal to minimally elevated left atrial pressure (5 to 15 mmHg) with evidence of adequate tissue and organ perfusion as defined by physical exam, urine output >1cc/kg/min, and no ongoing metabolic acidosis or lactic acidemia.

   Note 1: Ongoing metabolic acidosis caused by the continued production of lactic acid has been associated with a poor outcome following cardiac surgery in infants and children (Charpie et al., 2000 [C]; Munoz et al., 2000 [C]).

   Note 2: Continuous monitoring of arterial blood pressure via an arterial line is recommended (Local Expert Consensus [E]).

   Note 3: Continuous monitoring of left atrial pressure with a transthoracic catheter is recommended (Local Expert Consensus [E]).

Treatment Recommendations

2. It is recommended that milrinone be considered for any patient following arterial switch operation to prevent the occurrence of low cardiac output over the first 24 hours following arterial switch operation.

   Note: There is no direct evidence to suggest that routine use of milrinone following arterial switch operation improves outcome, but this recommendation is based on evidence that cardiac output decreases in the 6 to 18 hours following cardiopulmonary bypass (Wernovsky et al., 1995 [A]) and that phosphodiesterase inhibitors are effective in improving cardiac output after cardiopulmonary bypass (Hamada et al., 1999 [B]; Laitinen et al., 1999 [B]; Hoffman et al., 2003 [B]; Berner et al., 1990 [C]; Lynn et al., 1993 [C]; Bailey et al., 1997 [C]; Kikura et al., 1998 [C]).

3. It is recommended that milrinone be started for any patient with a left atrial pressure >15 mmHg or with signs or symptoms of low cardiac output. The recommended loading dose of milrinone is 50 mcg/kg over 30 to 60 minutes, followed by an infusion at 0.375 to 0.75 mcg/kg/min.

   Note 1: Direct comparison has failed to show any significant hemodynamic differences between inamrinone and milrinone. There are anecdotal reports of less thrombocytopenia with milrinone, so milrinone may be particularly useful for patients in whom phosphodiesterase inhibition is desired, but who are thrombocytopenic, or following surgery (Rathmell et al., 1998 [B]; Hamada et al., 1999 [B]).

Note 2: If hypotension develops, blood pressure support with other inotropic/vasopressor agents may be necessary (Lynn et al., 1993 [C]).

Definitions:

Cincinnati Children's Hospital and Medical Center Grading Scale:

A: Randomized controlled trial: large sample
B: Randomized controlled trial: small sample
C: Prospective trial or large case series
D: Retrospective analysis
E: Expert opinion or consensus
F: Basic laboratory research
L: Legal requirement
M: Meta-analysis or systematic review
O: Other evidence
Q: Decision analysis
S: Review article
X: No evidence

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and classified for each recommendation (see "Major Recommendations") using the following scheme:

Cincinnati Children's Hospital and Medical Center Grading Scale:

A: Randomized controlled trial: large sample
B: Randomized controlled trial: small sample
C: Prospective trial or large case series
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O: Other evidence
Q: Decision analysis
S: Review article
X: No evidence

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Clinically, phosphodiesterase inhibitors improve myocardial contractility, diastolic relaxation, and cause a decrease in afterload through vasodilation. These agents therefore improve cardiac index and lower left ventricular filling pressure after cardiopulmonary bypass, even in comparison to other inotropes or vasodilators.
- Phosphodiesterase inhibition is also of benefit in treating low cardiac output due to pulmonary hypertension, a complication known to occur after arterial switch operation. Because of these beneficial effects on afterload, myocardial function, and pulmonary vascular resistance, phosphodiesterase inhibition is a potentially useful treatment for neonates in low cardiac output after an arterial switch operation. Furthermore, it may be useful for prevention of a low cardiac output state in the patient who appears to be doing well, but this has not been extensively studied.

POTENTIAL HARMS

Hypotension may develop when using milrinone, which may necessitate blood pressure support with other inotropic/vasopressor agents

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These recommendations are based on the most current scientific information and have taken into consideration potential benefits, risks and side effects of treatment.
- In developing this guideline, the working group recognizes the paucity of large-scale studies with direct bearing on this particular focus population. The specific recommendations in this guideline are drawn from directly applicable studies where possible, but are largely extrapolated from smaller studies, and from studies more indirectly related to the present issues.
- These recommendations result from review of literature and practices current at the time of their formulations. This protocol does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the guidelines to meet the specific and unique requirements of individual patients. Adherence to this pathway is voluntary. The physician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Appropriate companion documents have been developed to assist in the effective dissemination and implementation of the guideline. Experience with the implementation of earlier publications of this guideline has provided information which has been incorporated into this revision.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan 22 (revised 2006 Jan 10)

GUIDELINE DEVELOPER(S)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

SOURCE(S) OF FUNDING

Cincinnati Children's Hospital Medical Center

GUIDELINE COMMITTEE

Cardiac Clinical Pathway Development Team 2006

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the Cardiac Clinical Pathway Development Team 2006

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Division of Health Policy & Clinical Effectiveness Support: Eloise Clark, MPH; Danette Stanko, MA, MPH, Epidemiologist; Kate Rich, Lead Decision Support Analyst; Carol Frese, RN, Medical Reviewer; Eduardo Mendez, RN, MPH, Dir. Evidence-Based Care; Edward Donovan, MD, Medical Director, Clinical Effectiveness

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Cincinnati Children's Hospital Medical Center Web site.

Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Children's Hospital Medical Center Health Policy and Clinical Effectiveness Department at HPCEInfo@chmcc.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 11, 2004. This NGC summary was updated by ECRI on June 21, 2006. The updated information was verified by the guideline developer on June 23, 2006.

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